## SETTLEMENT AGREEMENT BETWEEN THE DISTRICT OF COLUMBIA AND BAYER CORPORATION

- 1. This Agreement is between the District of Columbia ("the District") and the Bayer Corporation ("Bayer"), a corporation organized under the laws of Indiana, with headquarters in Pittsburgh, Pennsylvania.
- 2. The District alleges that beginning in about 1993, Bayer marketed and sold the biological products covered by this Agreement ("the Covered Drugs") using published average wholesale prices, wholesale acquisition costs, and actual acquisition costs for the products that were artificially inflated, resulting in artificially high prices being charged to agencies of the District. The District further alleges that Bayer knowingly misreported and underpaid its Medicaid Rebates for the Covered Drugs. The District alleges that in so doing, Bayer violated Federal and District statutes concerning, *inter alia*, unlawful trade practices, civil fraud and antitrust, as well as various common law rules. The Covered Drugs are Koate-HP Antihemophilic Factor (Human), Kogenate Antihemophilic Factor (Recombinant), Konyne 80 Factor IX Complex (Human), Gamimune N, 5% Immune Globulin Intravenous (Human, 5%), Gamimune N, 10% Immune Globulin Intravenous (Human, 10%), Thrombate III Antithrombin III (Human). This Agreement covers all sales of the Covered Drugs up to the date of this Agreement.
- 3. Bayer denies all the allegations of the District described above, and enters into this Agreement solely to bring about an amicable resolution of the claims of the District and to bring the District within the ambit of similar litigation settlements previously reached by Bayer with some state governments (Civil Action No. 95-95 1354 (S.D. Fla.)). This Agreement does not constitute an admission by Bayer or evidence of any liability or wrongful conduct.
- 4. Bayer agrees to pay \$35,000 to the District, for deposit in the District of Columbia Antitrust Fund (D.C. Official Code, § 28-4516 (2001)). In return, the District releases Bayer, its parent corporations, subsidiaries, affiliates, predecessors, successors and assigns, as well as its current and former directors, officers, employees and agents from any monetary or administrative claim, action, suit or proceeding the District may have under any source of law as a consequence of the allegations described above with regard to the Covered Drugs. The payment of this settlement amount fully discharges Bayer from any obligation to pay restitution, damages, and/or any fine to the District for this alleged conduct.
- 5. The District agrees that it will not pursue any administrative claim, action, suit or other administrative proceeding against Bayer, its parent corporations, subsidiaries, affiliates, predecessors, successors and assigns, as well as its current and former directors, officers, employees and agents, seeking as a consequence of the allegations described

above with regard to the Covered Drugs the exclusion of any of Bayer's products from the District's formulary, or use of prior authorization requirements for any of Bayer's products, or suspending or debarring Bayer from any contracts with the District.

- 6. Bayer represents that it will report certain drug and biological product pricing information to the District's Medicaid agency, the Medical Assistance Administration in the District's Department of Health (hereafter "District Medicaid Program"), as described in (a) through (c) below, for the purpose of furnishing the District with true pricing information that accurately reflects the prices at which actual purchasers buy the drug products sold by Bayer. Bayer understands that this information may be relied upon by the District in establishing reimbursement rates for drugs and biological products. The District acknowledges Bayer's representations and their stated purpose of providing accurate and truthful information, without waiver or prejudice to the District's right to make claims against Bayer for any conduct of Bayer occurring after the date of this Agreement.
- (a) Price Reporting: Thirty days after the last day of each calendar quarter, Bayer shall report, in accordance with sub-paragraph (b), the average sale price of each of its drugs and biological products identified by Bayer's NDC codes that are or shall be reimbursed by the District Medicaid Program, to First DataBank and to the District Medicaid Program. If appropriate to reflect changes in the sources from which the District Medicaid Program receives its pricing information, Bayer agrees that, upon the receipt of a written request from the District, it will report the prices to a drug pricing reporting source other than, and in addition to, First DataBank, subject to reasonable provisions equivalent to those in place with First DataBank to ensure the confidentiality of that information.
- (b) Average Sale Price Reporting Procedure: The price reported by Bayer with respect to each dosage form, strength and volume of the drug or biological product (without regard to any special packaging, labeling, or identifiers on the dosage form or product or package), shall be the average of all final sale prices charged by Bayer for the drug in the United States to all purchasers, excluding those sales exempt from inclusion in the calculation of "Best Price" for Medicaid Rebate Program purposes, pursuant to 42 USC § 1396r-8, and direct sales to hospitals. The prices identified in the calculation of the average sale price should be net of all the following: volume discounts; prompt pay discounts; cash discounts; chargebacks; short-dated product discounts; free goods; rebates (excluding from the term "rebate" as used here any payments made by Bayer to the States pursuant to the Medicaid Rebate Program) and all other price concessions provided by Bayer to any relevant purchaser, as earlier defined in this paragraph, that result in a reduction of the ultimate cost to the purchaser. Notwithstanding the foregoing, the average sale price shall not include the value of bona fide charity care or grants. The average sale price reported shall be properly weighted to reflect the volume of sales at each sale price, i.e., for each NDC code, the price reported shall be an average per unit price determined by dividing the total of all final prices charged by Bayer, net of all price reductions as defined above, for a drug or biological product in a quarter by the total number of units of that drug or biological product sold in that quarter. The methodology

by which Bayer has calculated average sale prices in accordance with these standards shall be identified to the District.

- (c) Limitations on Reporting of Average Wholesale Price: With respect to the Covered Drugs, Bayer shall not report an AWP to First DataBank, or any other reporting service, to be used for purposes of setting Medicaid reimbursement prices for the Covered Drugs, and Bayer shall expressly inform such reporting services to this effect. This restriction shall not limit Bayer's ability to report AWP information for the Covered Drugs to price reporting services for uses unrelated to Medicaid, or its ability to report AWP information for any purposes for drugs or biological products other than the Covered Drugs.
- (d) Certification: With each report of average sale price information, Bayer shall also provide First DataBank and the District Medicaid Program with a detailed description of the methodology used to calculate the average sale price. A high managerial agent of Bayer will certify that the average sale prices reported therein are calculated in accordance with the described methodology. Said certification shall include an acknowledgment that the average sale prices reported will be filed with and used in the administration of the District Medicaid Program.
- (e) Bayer considers the average sale price information and the methodology by which it is calculated to be confidential commercial information and proprietary trade secrets that if disclosed would cause substantial injury to the competitive position of Bayer. However, all information provided by Bayer to the District Medicaid Program pursuant to this Agreement shall be made available to the District Medicaid Fraud Control Unit upon request.
- (f) Bayer shall comply with the provisions of Paragraph 6 for a period of three years from the Effective Date of this Agreement.

  Bayer shall retain all workpapers and supporting documentation relating to the average sale prices of its drugs for four years after the date of each certification and will make such documentation available for inspection by the District Medicaid Program and the District's Office of the Inspector General, Medicaid Fraud Control Unit.
- 7. Nothing in this Agreement shall be construed as a waiver by Bayer of its attorney-client privilege or work product privilege.
- 8. Unless otherwise stated in writing subsequent to the Effective Date of this Agreement, which shall be the latest date on which any signatory signs this Agreement, all notifications and communications made to Bayer pursuant to this Agreement shall be made to:

Assistant General Counsel Bayer Corporation Pharmaceutical Division 400 Morgan Lane West Haven, CT 06516

- 9. This Agreement, including all exhibits, constitutes the complete agreement between the parties and may not be amended except by written consent of the parties.
- 10. The entire text of this Agreement will be made available to the public on the web site of the Office of the Corporation Counsel of the District of Columbia.

For the District of Columbia:

For the Bayer Corporation:

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Dated:

April 28, 2003